

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: PETER L. HARRIS, et al.	)	Confirmation No: 3111
	)	
Application No.: 10/603,952	)	Group Art Unit: 3738
	)	
Filed: June 25, 2003	)	Examiner: WILLSE, D.

For: VASCULAR PROSTHESIS

United States Patent and Trademark Office  
Customer Service Window, Mail Stop AF  
Randolph Building  
401 Dulany Street  
Alexandria, Virginia 22314

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

Applicants request review of the Final Rejection mailed April 16, 2007. This request is filed concurrently with a Notice of Appeal, and no amendments are being filed with this request. The review is requested for the reasons provided below. A Notice of Appeal and a petition for extension of time accompanies this request.

Claims 1-11 and 14-24 are pending in this application. The 35 U.S.C. §112 rejection of claim 4 has been withdrawn by the September 4, 2007 Advisory Action. Claims 1-5, 7-11, 14, 16, 18, 19, and 21 stand rejected under 35 U.S.C. §102(b) over Rayhanabad (U.S. Pat. No. 4712551); claims 6, 15, 17, 20, and 22 stand rejected under 35 U.S.C. §103(a) over Rayhanabad; and claims 23-24 stand rejected under 35 U.S.C. §102(e) over Butters (U.S. Pat. No. 6019788). Claims 1, 18, 21, and 23 are the independent claims.

**I. The Final Rejection Fails To Establish A Rejection Under 35 U.S.C. §102(b)**

Independent claims 1, 18, and 21 stand rejected under §102(b) over Rayhanabad. A §102(b) rejection requires, among other things, that each and every element of the rejected claim be found in the applied reference. *See* MPEP §2131.

Claim 1 regards a vascular prosthesis having, among other things, a tubular portion and an end formation. The end formation defines an enlarged chamber. The enlarged chamber has a

non-circular open end perimeter. The non-circular open end perimeter outlines a cross-sectional area that is larger than a cross-sectional area of the tubular portion at a first diameter.

Claim 18 regards a vascular prosthesis having, among other things, a tube and an enlargement. The enlargement defines an enlarged chamber. The enlarged chamber has a non-circular open end perimeter. The non-circular open end perimeter outlines a cross-sectional area that is larger than a cross-sectional area of the first diameter portion of the tube.

Claim 21 regards a vascular prosthesis having, among other things, a tube and first and second enlargements. At least one of the first and second enlargements defines an enlarged chamber. The enlarged chamber has a non-circular open end perimeter. The non-circular open end perimeter outlines a cross-sectional area that is larger than a cross-sectional area of the first diameter portion of the tube.

Claims 1, 18, and 21 thus each recite "a non-circular open end perimeter of an enlarged chamber." This recitation defines the perimeter to be (1) non-circular and (2) at an open end of an enlarged chamber.

The only non-circular structure described in Rayhanabad is mouth 22, which is shown and described as having an elliptical cross section. *See* Rayhanabad at col. 5 (lines 26-28) and Fig. 2. However, the Office (at page 5 of the Final Rejection) has stated that it does not consider mouth 22 to be the recited non-circular open end perimeter.

Instead, the Final Rejection at pages 3 and 5 asserts that a non-circular open end perimeter is found in Rayhanabad's shunt 10 at the outermost radial extent of balloon 32. Specifically, the Office asserts that the radially-outermost limits of balloon 32 "defines a non-circular open-end perimeter." However, Rayhanabad's balloon 32 is not shown or described to have a non-circular perimeter and, from Rayhanabad's drawings, balloon 32 appears to have a circular perimeter. Rayhanabad thus fails to show or describe a non-circular open end perimeter, and the Office has not established a *prima facie* rejection under §102(b).

## **II. The Final Rejection Fails To Establish A Rejection Under 35 U.S.C. §102(e)**

Independent claim 23 stands rejected under §102(e) over Butters. MPEP §2136.02(II) states (emphasis added):

When a U.S. patent, a U.S. patent application publication, or an international application publication is used to reject claims under

35 U.S.C. 102(e), the disclosure relied on in the rejection must be present in the issued patent or application publication.

Claim 23 regards, among other things, a vascular prosthesis having a continuous expanded polytetrafluoroethylene structure with a generally uniform surface.

Butters shows and describes a series of separate components joined together to form device 10. As shown in Fig. 3 of Butters, device 10 is made of a cuff 28 that is heat sealed to conduit 16. *See* Butters at col. 8, line 4. Butters also shows that the structure of device 10 lacks a generally uniform surface because cuff 28 joins conduit 16 to form a non-uniform surface on, at least, the exterior of device 10. Accordingly, Butters thus fails to show or describe a continuous expanded polytetrafluoroethylene structure, or a structure with a generally uniform surface.

Claim 23 also regards, among other things, a vascular prosthesis with a structure having an enlargement defining an enlarged chamber.

As shown in Butters at Figs. 8A-8E, the conduit 16 extends through cuff 28 and thus maintains a constant inner diameter along the length of device 10. Butters also describes cuff 28 to surround conduit 16, and thus does not form a part of the interior of conduit 16. *See* Butters at col. 7 (line 5). Butters thus fails to show or describe cuff 22 defining an enlarged chamber in the Butters device as the interior dimensions of the Butters device do not change along conduit 16.

The Office's assertions regarding the enlargement of conduit 16 (for claim 23) are also inconsistent with the interpretation of Butters that is applied to claim 24 (discussed below). Specifically, in the rejection of claim 23, the Office asserts that conduit 16 has an enlargement and, in the rejection of claim 24, the Office simultaneously asserts that the same conduit 16 would inherently have a reduced diameter. Both statements are mutually exclusive and, one or both must be erroneous (Applicants assert that both are wrong because conduit 16 has a constant diameter).

Butters thus fails to show or describe a continuous structure with a uniform surface, or a structure with an enlargement defining an enlarged chamber. For at least these reasons, the Office has not established a *prima facie* rejection under §102(e).

**III. The Final Rejection Fails To Establish Inherency In Support Of A Rejection Under 35 U.S.C. §102(e)**

Dependent claim 24 stands rejected under §102(e) over Butters in combination with an assertion of inherency regarding the Butters device. Specifically, the Final Rejection at page 4 asserts that "a reduced diameter of the tubular part 16 within cuff 28 would have been inherent from the sealing attachment of the cuff onto the tubular part ... and/or from the fact that the blood conduit 16 can be stepped" (emphasis added). As explained below, the asserted arrangement is not inherent in Butters. Furthermore, the Office's assertions regarding inherency are inconsistent with the interpretation of Butters presented with regard to the rejection of claim 23 (for the reasons discussed above with regard to the §102(e) rejection of claim 23).

MPEP §2112(IV) states that:

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Butters states that the "cuff 28 may be provided on the conduit 16 to further improve the anchoring" of the conduit to a blood vessel (*see* Butters at col. 7 (lines 1-3)) and states that conduit 16 "may be provided in straight, tapered, stepped, or other forms" (*see* Butters at col. 7 (lines 43-44)). However, the mere fact that these features may possibly exist in the Butters device is not sufficient to establish inherency and, even if present, the features do not necessarily create a "reduced diameter". Furthermore, the portions of Butters cited by the Office do not establish that the allegedly-inherent "reduced diameter" feature is disposed on the Butters device 10 "adjacent" to an "enlargement" as recited in claim 24.

The Office Action thus fails to establish inherency because the allegedly-inherent "reduced diameter" feature is not necessarily present in the Butters device 10. For at least this reason, the Office has not established a *prima facie* rejection under §102(e).

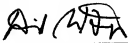
## CONCLUSION

For at least the foregoing reasons, the Office has failed to establish *prima facie* rejections under 35 U.S.C. §102(b) and §102(e) because Rayhanabad and Butters each do not show or describe the features recited in the independent claims, or the dependent claims thereof. The Office has also failed to establish a *prima facie* case rejection of claim 24 because the rejection depends on an assertion on inherency that has not been established under MPEP §2112(IV). It is thus respectfully requested that the rejections be withdrawn.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,

*For:*  (Reg. No. 53,964)  
David W. Laub  
Attorney for Applicants  
Reg. No.: 38,708

Date: September 17, 2007  
Patent Administrator  
**Proskauer Rose LLP**  
1001 Pennsylvania Avenue, NW  
Suite 400  
Washington, DC 20004  
Telephone: 202.416.6800  
Facsimile: 202.416.6899  
CUSTOMER NO: 61263

Customer No. 61263